Delayed Complication from a Percutaneous Vascular Closure Device Following a Neuro-Interventional Procedure

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Summary

Percutaneous vascular closure devices are being increasingly used as alternatives to manual compression for the closure of femoral arteriotomy after endovascular procedures as they appear to reduce time to ambulate, improve patient's comfort, and are implicated with cost saving. However, vascular closure devices have been associated with an increased risk of complications including hematoma formation, local bleeding, arteriovenous fistula formation, pseudoaneurysm and arterial leg ischemia. To our knowledge, if the above complications occur it is usually within the first 30 days after the procedure. None have been reported in a delayed fashion ten months or longer after closure. We describe a 30-year-old man with a history of a giant basilar trunk aneurysm. He was placed on aspirin and clopidogrel prior to the procedure. He had bilateral femoral access with 6 French sheaths. Following the procedure, 6 French Angio-Seals (St. Jude Medical, St. Paul, MN, USA) were used for closure of bilateral femoral arteriotomies. Ten months after the procedure, the patient kicked a metal cart and developed a large right retroperitoneal iliopsoas hematoma. There was no evidence of pseudoaneurysm. The patient was managed conservatively and his serial hematocrit stayed stable. He did not require surgical intervention.

Use of percutaneous vascular closure devices is associated with complications including risk of hematoma, pseudoaneurysm, intravenous fistula, rectal peritoneal hemorrhage, limb ischemia and possible surgical repair. Most complications occur peri-procedure or within 30 days post-procedure. This is the first reported case of a delayed complication at ten months after the initial procedure.

Site-related complications associated with percutaneous vascular closure devices may occur in a delayed fashion, even ten months post-procedure, so should be considered in the management of patients.

Introduction

Interventional neuroangiography is commonly performed via the common femoral artery as an access site. Hemostasis at the arteriotomy site following the procedure has been traditionally achieved with manual compression at the site of the catheter sheath. Manual compression is considered to have a low complication rate but it also involves bed rest as well as discomfort to the patient. The use of percutaneous vascular closure devices has emerged as an alternative to manual compression in achieving hemostasis in a safe and timely manner while reducing time to ambulate and improving patients' comfort. The complications of using percutaneous vascular closure devices include hematoma, local bleeding, arteriovenous fistual formation, pseudoaneurysm and
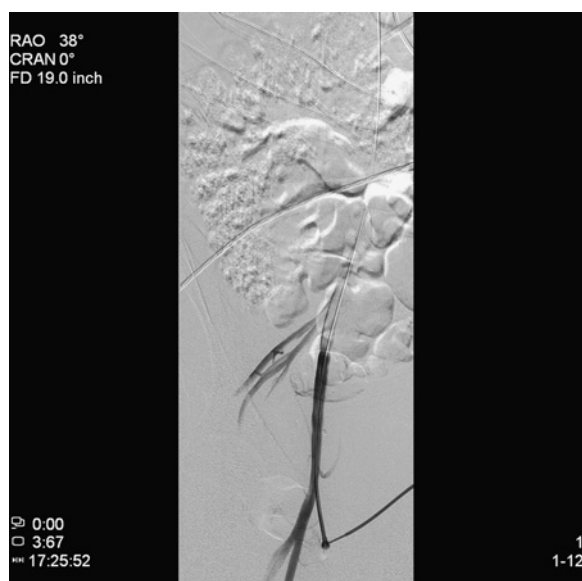
Figure 1 Right femoral artery run indicating the 6F catheter sheath in a position proximal to the femoral bifurcation and distal to the inferior epigastric artery.

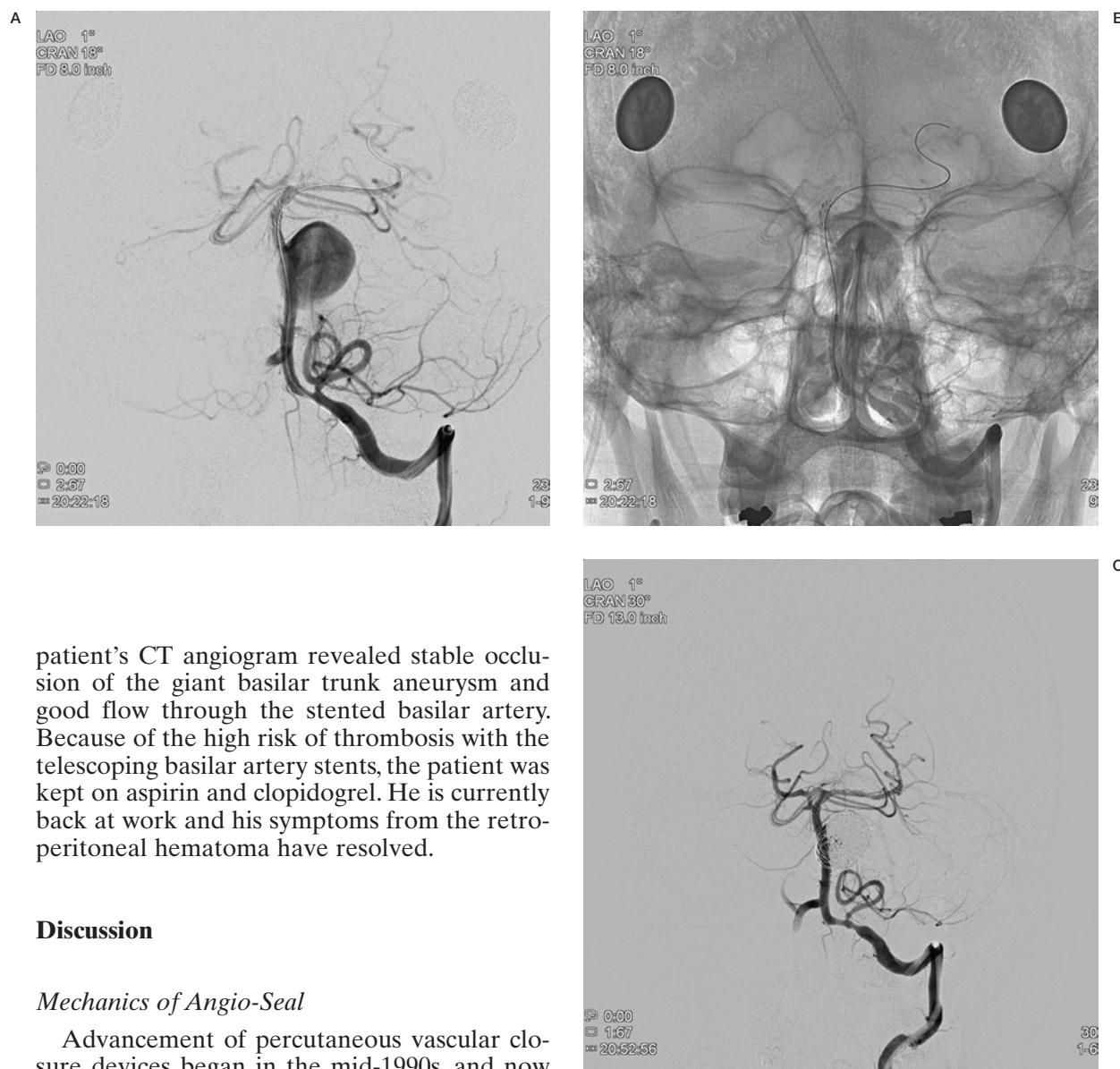*Figure 2* Left vertebral artery run with a large midbasilar aneurysm.

arterial leg ischemia. Management of these complications includes conservative treatment, blood transfusion and occasionally surgical repair. Almost all of the above complications have been noted either peri-procedure (during the patient hospital stay) or early (within 30 days of procedure). There are no reports in the literature of late (greater than 30 days) complications from percutaneous vascular closure devices. To our knowledge, this is the first documented case report of a delayed (ten months) complication from an arteriotomy site following the use of a percutaneous vascular closure device.

Case Report

A healthy 30-year-old man with a social history of cocaine abuse woke up with the worst headache of his life and right hemiparesis and numbness, slurred speech and double vision. Head computed tomography (CT) and CT angiography revealed a giant basilar trunk aneurysm measuring 2.3×2.3 cm with compression of the brainstem and fourth ventricle causing ventriculomegaly. On neurologic examination, the patient had profound right hemiparesis (3/5). He underwent right frontal ventriculoperitoneal shunt placement to treat his hydrocephalus and two days later underwent endovascular treatment for the giant basilar trunk

aneurysm. He was placed on aspirin and clopidogrel for stent-assisted coiling of the basilar aneurysm. In the endovascular suite, bilateral femoral artery access was performed with bilateral 6 French sheaths. After angiography confirmation of proper femoral artery sheath placement, intravenous systemic heparinization was started. Stent-assisted coiling of the giant basilar trunk aneurysm was performed using four telescoping Enterprise vascular reconstruction devices (Codman Neurovascular, San Jose, CA, USA), four Micrus Presidio Cerecyte coils (Micrus Endovascular, San Jose, CA, USA), and five Codman Orbit coils (Codman Neurovascular). At the end of the procedure, bilateral femoral arteriotomies were closed using 6 French Angio-Seal (St. Jude Medical, Inc., St Paul, MN, USA) closure devices. The patient had immediate improvement of his right hemiparesis and was discharged home.

He was able to return to work full time. Ten months following his procedure, he kicked a metal cart at work that resulted in right abdominal and thigh pain. CT of the abdomen revealed a large 10.3×8.1 cm in maximum transverse dimensions and 17.5 cm craniocaudally right retroperitoneal and iliopsoas hematoma with no evidence of active arterial or venous extravasation. There was no evidence of pseudoaneurysm. The patient was followed conservatively and his serial hematocrit remained stable and he required no blood transfusion. The

Figure 3 A) Left vertebral artery run with a microwire extending into the basilar artery and into the left posterior cerebral artery. B) Placement of the stent in the basilar artery across the large aneurysm. C) Left vertebral artery run following stent/coiling of the midbasilar aneurysm.

patient's CT angiogram revealed stable occlusion of the giant basilar trunk aneurysm and good flow through the stented basilar artery. Because of the high risk of thrombosis with the telescoping basilar artery stents, the patient was kept on aspirin and clopidogrel. He is currently back at work and his symptoms from the retroperitoneal hematoma have resolved.

Discussion

Mechanics of Angio-Seal

Advancement of percutaneous vascular closure devices began in the mid-1990s, and now there are multiple vascular closure devices such as Mynx (AccessClosure, Inc., Mountain View, CA, USA), Starclose (Abbot Vascular, Redwood City, CA, USA), Perclose (Abbot Vascular, Redwood City, CA, USA), and Angio-seal. Angio-Seal is one of the most widely used devices to date. The Angio-Seal device consists of an absorbable anchor and a collagen sponge connected by an absorbable positioning Dexon suture. The original design was introduced in Europe in 1994. The device has undergone multiple modifications to allow for more consistent deployment. The Angio-Seal sheath is first introduced inside the artery with the assistance of a guidewire then the dilator and guide wire are removed. Then the Angio-Seal device is introduced into the sheath which includes an intra-arterial absorbable anchor and a collagen plug. The anchor lies within the vessel wall while the plug is sandwiched between the arterial wall and the puncture site by traction on a suture and by pushing on a small plastic tube that is also threaded over the suture to provide counter traction. The particular model of Angio-Seal that was used in this case is called Angio-Seal VIP. Since this procedure, the device
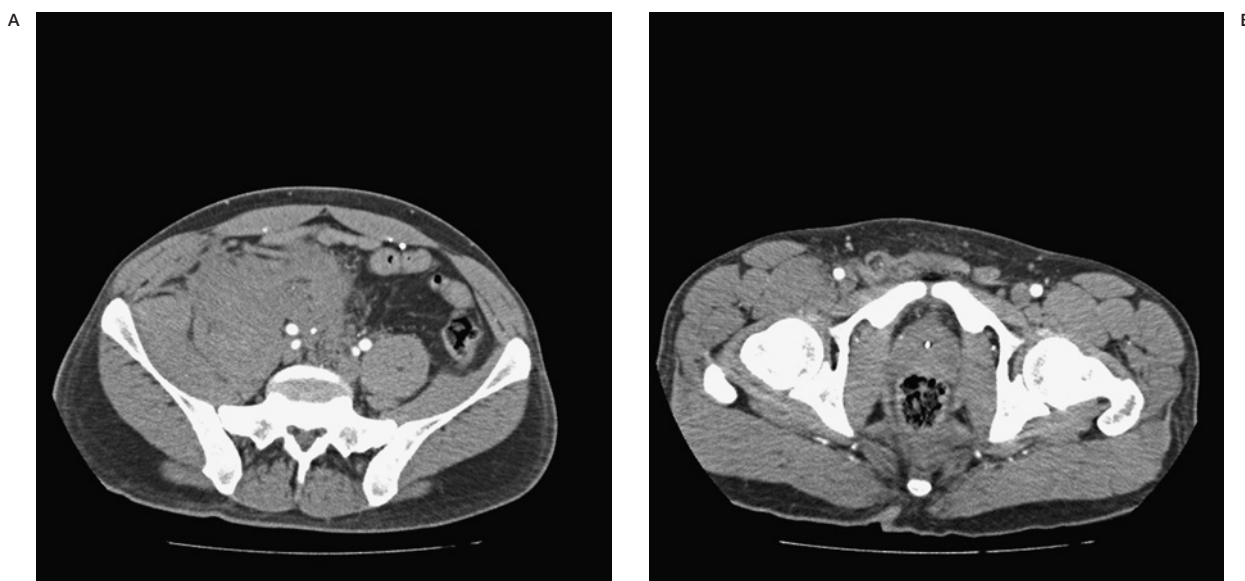
Figure 4 A) CT abdomen revealing a large right-sided retroperitoneal hematoma. B) CT pelvis with right femoral artery without active extravagation of contrast.

has been upgraded to Angio-Seal-Evolution which allows for a more consistent collagen compaction. The material is absorbed within 60-90 days according to the manufacturer.

Complications from Vascular Closure Devices

Despite decreasing time to hemostasis and time to ambulate, vascular closure devices may result in a number of complications such as arterial thromboses, infection, dissection, pseudoaneurysms, hematoma formation, local bleeding, arteriovenous fistula formation and arterial leg ischemia. Many factors increase the risk of complications from VCD including anticoagulation, antiplatelet medication, older age and the presence of an in-dwelling sheath for extended time. Most of the literature studies on VCD complications were related to coronary patients. A major concern for interventional neuroradiologists is the need for their patients to be anticoagulated during the procedure and to be on antiplatelet drugs following the procedure. As in our case, the patient underwent intracranial stenting which necessitated aspirin, clopidogrel and systemic intravenous heparnization. The patient continued on aspirin and clopidogrel following discharge, and when he presented with the retroperitoneal hematoma ten months following his procedure, he was still taking his aspirin and clopidogrel.

Manual compression for femoral hemostatis is thought to have a low complication rate. Overall complications from manual compression are estimated to be around 8%, of which 4% are hematomas. The other 4% of complications include pseudoaneurysms (3%) and arteriovenous fistulas (1%) as diagnosed with ultrasound two days after coronary interventional procedures.

The use of VCDs adds additional complications that are associated with the use of the devices such as infection, vessel occlusion, distal emboli and injury to the nerve. However, early meta-analysis studies revealed that the use of VCDs such as Angio-Seal did not increase the risk of access site-related complications. Others found an increased risk of hematoma formation and pseudoaneurysm formation following the application of VCD at the arterial site but there was a high degree of heterogeneity among the studies.

Successful deployment of VCD is limited by the initial arterial puncture and the anatomy of the vessel where failure is associated with age, peripheral arterial disease and diabetes. Failure of VCD deployment is associated with an increase in both major (retroperitoneal hemorrhage, limb ischemia, or any surgical repair) and minor (groin bleeding, hematoma greater than 5 cm, pseudoaneurysm or arteriovenous fistula) complications. There is a 3.2 fold increase in major complications and a 5.4 fold increase in minor complications following failure of VCD deployment. However, as mentioned above, this

patient had a successful deployment of his Angio-Seal which places him at a lower risk for minor as well major complications.

Major vascular complications from Angioseal are thought to be around 2.1% and include malfunctioning device 1.1%, hemorrhage requiring intervention 0.5% and hemorrhage with a loss of > 3 g of hemoglobin is around 0.5%. Minor complications include hematoma > 5 cm (0.5%) and procedure failure within 30 minutes requiring manual compression (3.7%).

We did find one study with a long-term follow-up of antegrade and retrograde deployment of Angio-seal as well as manual compression. The long-term follow-up (1-36 months) at 18 months was 0% while the overall complication for antegrade puncture closure at 30 was 2.5%, which is similar to other studies. Again, to our knowledge, this is the first case report of delayed complication (> 30 days) from a percutaneous vascular closure device.

Retroperitoneal Hematoma

Retroperitoneal hemorrhage occurs in 0.5%-0.75% following access to the common femoral artery for vascular and coronary procedures. Risk factors for retroperitoneal hematoma include female gender, low body surface area and high femoral artery puncture site. The presence of retroperitoneal hematoma in cases with arterial puncture distal to the inferior epigastric artery and thus below the inguinal ligament might be related to the spread of bleeding along the anatomic fascial planes. In our case,

the risk factors for this patient were very low as he was male with a normal body surface area and his puncture site was below the epigastric artery. The Angioseal closure device is not recommended for use when the arterial puncture site is proximal to the inferior epigastric artery. It is speculated that the collagen plug in the Angioseal can be stuck between the various layers of abdominal wall leading to a temporary hemostasis but then can cause a retroperitoneal hematoma when the layers of muscle and fascia are separated from the artery. As mentioned above, this occurs in the acute and early post-procedure period but not likely to occur in a delayed fashion (<6 months).

Spontaneous retroperitoneal hematoma is rare with only 34 cases reported in the literature. The vast majority of the cases occurred in postmenopausal women and involved the left iliac region indicating that there is an association with hormonal factors as well as mechanical factors. Weakening of the vessel wall due to intimal changes can contribute to potential predisposing mechanical factors that could lead to spontaneous retroperitoneal hemorrhage. Minor trauma, such as in this case, can theoretically be associated with retroperitoneal hematoma, but there are no such reports in the literature. One can also speculate that following the use of a vascular closure device, the integrity of the arterial wall is somewhat compromised and a mechanical risk factor predisposes this patient for a possible spontaneous retroperitoneal hematoma.

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